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TOWNSEND and TOWNSEND and CREW LLP  
By: Jay A. Berzofsky

**PATENT**  
Attorney Docket No.: 015280-368240US  
Client Reference No.: E-268-1997/2-US-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jay A. Berzofsky *et al.*

Application No.: 10/815,340

Filed: March 30, 2004

For: MUCOSAL CYTOTOXIC T  
LYMPHOCYTE RESPONSES

Confirmation No.: 8261

Examiner: Nicole Kinsey

Art Unit: 1645

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Parent Application No. 09/508,552, filed March 9, 2000 (now U.S. Patent No. 6,749,856, issued on June 15, 2004; Attorney Docket No. 015280-368200US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

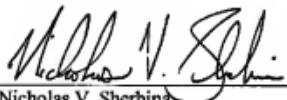
representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Date: March 30, 2007

By:

  
Nicholas V. Sherbina  
Reg. No. 54,443

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81015199 v1

Substitute for Form 1449A&B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/815,340
				Filing Date	March 30, 2004
				First Named Inventor	Berzofsky, Jay A.
				Art Unit	1645
				Examiner Name	Nicole Kinsey
(Use as many sheets as necessary)				Attorney Docket Number	015260-368240US
Sheet	1	of	5		

**U.S. PATENT DOCUMENTS**

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**FOREIGN PATENT DOCUMENTS**

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FOREIGN PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Column, Line, Where Relevant Passage or Relevant Figures Appear
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)		
AE		PCT	WO 87/07616		12/17/1987	
AF		PCT	0 273 716		12/23/1987	
AG		PCT	WO 94/26785		11/24/1994	

Examiner Signature		Date Considered	
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Considered: Initial copy or the form with next communication to applicant. <sup>2</sup> Applicant's unique citation designation number (optional). <sup>3</sup> Applicant is to place a check mark here if English language Translation is attached.

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			Application Number	10/815,340	
			Filing Date	March 30, 2004	
			First Named Inventor	Berzofsky, Jay A.	
			Art Unit	1645	
			Examiner Name	Nicole Kinsey	
Sheet	2	of	5	Attorney Docket Number	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	AH	Ahlers <i>et al.</i> , "Construction of an HIV-1 Peptide Vaccine Containing a Multideterminant Helper Peptide Linked to a V3 Loop Peptide 18 Inducing Strong Neutralizing Antibody Responses in Mice of Multiple MHC Haplotypes after Two Immunizations," <i>J. Immunol.</i> 150:5647-5665 (1993).			<input type="checkbox"/>
	AI	Ahlers <i>et al.</i> , "Candidate HIV Type 1 Multideterminant Cluster Peptide-P18MN Vaccine Constructs Elicit Type 1 Helper T Cells, Cytotoxic T Cells, and Neutralizing Antibody, all Using the Same Adjuvant Immunization," <i>AIDS Res. Hum. Retroviruses</i> 12:259-272 (1996).			<input type="checkbox"/>
	AJ	Ahlers <i>et al.</i> , "Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV-1 Vaccine Constructs," <i>J. Immunol.</i> 158:3947-3958 (1997).			<input type="checkbox"/>
	AK	Ahlers <i>et al.</i> , "Enhanced Immunogenicity of HIV-1 Vaccine Construct by Modification of the native Peptide Sequence," <i>Proc. Natl. Acad. Sci. USA</i> 94:10856-10861 (1997).			<input type="checkbox"/>
	AL	Belyakov <i>et al.</i> , "Mucosal Immunization with HIV-1 Peptide Vaccine Induces Mucosal and Systemic Cytotoxic T Lymphocytes and Protective Immunity in Mice Against Intrarectal Recombinant HIV-Vaccinia Challenge," <i>Proc. Nat. Acad. Sci.</i> 95:1709-1714 (1998).			<input type="checkbox"/>
	AM	Berzofsky <i>et al.</i> , "Construction of Peptides Encapsulating Multideterminant Clusters of Human Immunodeficiency Virus Envelope to Induce <i>In Vitro</i> T Cell Responses in Mice and Humans of Multiple MHC Types," <i>J. Clinical Invest.</i> 88:876-884 (1991).			<input type="checkbox"/>
	AN	Berzofsky and Berkower, "Novel Approaches to Peptide and Engineered Protein Vaccines for HIB Using Defined Epitopes: Advances in 1994-1995," <i>AIDS</i> 1995 9(A):S143-S157 (1995).			<input type="checkbox"/>
	AO	Bonsel, "Transcytosis of Infectious Human Immunodeficiency Virus Across a Tight Human Epithelial Cell Line Barrier," <i>Nature Medicine</i> 3:42-47 (1997).			<input type="checkbox"/>
	AP	Butini <i>et al.</i> , "Comparative Analysis of HIV-Specific CTL Activity in Lymphoid Tissue and Peripheral Blood," <i>J. Cellular Biochemistry Abstract Supplement</i> :147 (1994).			<input type="checkbox"/>
	AQ	Cranage <i>et al.</i> , "Macaques Infected with Live Attenuated SIVmac are Protected Against Superinfection via the Rectal Mucosa," <i>Virology</i> 229:143-154 (1997).			<input type="checkbox"/>

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Art Unit	1645
				Examiner Name	Nicole Kinsey
Sheet	3	of	5	Attorney Docket Number	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), site of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	AR	di Tommaso <i>et al.</i> , "Induction of Antigen-Specific Antibodies in Vaginal Secretions by Using a Nontoxic Mutant of Heat-Labile Enterotoxin as a Mucosal Adjuvant," <i>Infection and Immunity</i> 64:974-979 (1996).			<input type="checkbox"/>
	AS	Douce <i>et al.</i> , "Intranasal Immunogenicity and Adjuvanticity of site-directed mutant derivatives of cholera toxin," <i>Infection and Immunity</i> 65:2821-2828 (1997).			<input type="checkbox"/>
	AT	Gallichan <i>et al.</i> , "Long-Lived Cytotoxic T Lymphocyte Memory in Mucosal Tissues After Mucosal but not Systemic Immunization," <i>J. Exp. Med.</i> 184:1879-1890 (1996).			<input type="checkbox"/>
	AU	Graham <i>et al.</i> , "Candidate AIDS Vaccines," <i>New England Journal of Medicine</i> 333:1331-1339 (1995).			<input type="checkbox"/>
	AV	Hale <i>et al.</i> , "T Cell Multideterminant Regions in the Human Immunodeficiency Virus Envelope: Toward Overcoming the Problem of Major Histocompatibility Complex Restriction," <i>International Immunology</i> 1:409-415 (1989).			<input type="checkbox"/>
	AW	Haynes, B.F., "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development," <i>Science</i> 260:1279-1286 (1993).			<input type="checkbox"/>
	AX	Klavinskis <i>et al.</i> , "Mucosal or Targeted Lymph Node Immunization of Macaques with a Particulate SIVp27 Protein Elicits Virus-Specific CTL in the Genito-Rectal Mucosa and Draining Lymph Nodes," <i>J. Immunol.</i> 157:2521-2527 (1996).			<input type="checkbox"/>
	AY	Kozlowski <i>et al.</i> , "Serum Angiotensin-I Converting Enzyme Activity Processes a Human Immunodeficiency Virus 1 Gp160 Peptide for Presentation by Major Histocompatibility Complex Class I Molecules," <i>J. Exp. Med.</i> 175:1417-1422 (1992).			<input type="checkbox"/>
	AZ	Langermann, S., "New Approaches to Mucosal Immunization," <i>Seminars in Gastrointestinal Disease</i> 7:12-18 (1996).			<input type="checkbox"/>
	BA	Lehner <i>et al.</i> , "Protective Mucosal Immunity Elicited by Targeted Iliac Lymph Node Immunization with a Subunit SIV Envelope and Core Vaccine in Macaques," <i>Nature Medicine</i> 2:767-775 (1996).			<input type="checkbox"/>

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				Filing Date	March 30, 2004
				First Named Inventor	Berzofsky, Jay A.
				Art Unit	1645
				Examiner Name	Nicole Kinsey
Sheet	4	of	5	Attorney Docket Number	015280-368240US

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
	BB	Miller <i>et al.</i> , "Genital Mucosal Transmission of Simian Immunodeficiency Virus: Animal Model for Heterosexual Transmission of Human Immunodeficiency Virus," <i>J. Virol.</i> 63:4277-4284 (1989).				<input type="checkbox"/>
	BC	Modrow <i>et al.</i> , "Computer-Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," <i>J. Virol.</i> 61:570-578 (1987).				<input type="checkbox"/>
	BD	Musey <i>et al.</i> , "HIV-1 Induces Cytotoxic T Lymphocytes in the Cervix of Infected Women," <i>J. Exp. Med.</i> 185:293-300 (1997).				<input type="checkbox"/>
	BE	Neutra <i>et al.</i> , "Antigen Sampling Across Epithelial Barriers and Induction of Mucosal Immune Responses," <i>Annu. Rev. Immunol.</i> 14:275-300 (1996).				<input type="checkbox"/>
	BF	Parditos <i>et al.</i> , "Antibody Responses to Non-Immunogenic Synthetic Peptides Induced by Co-Immunization with Immunogenic Peptides," <i>Immunology</i> 77:262-266 (1992).				<input type="checkbox"/>
	BG	Parditos <i>et al.</i> , "Mucosal Immunization with a Measles Virus CTL Epitope Encapsulated in Biodegradable PLG Microparticles," <i>J. Immun. Meth.</i> 195:135-138 (1996).				<input type="checkbox"/>
	BH	Parditos <i>et al.</i> , "The Adjuvant Effect of a Non-Toxic Mutant of Heat-Labile Enterotoxin of <i>Escherichia Coli</i> for the Induction of Measles Virus-Specific CTL Responses After Intranasal Co-Immunization with a Synthetic Peptide," <i>Immunology</i> 89:483-487 (1996).				<input type="checkbox"/>
	BI	Porgador <i>et al.</i> , "Intranasal Immunization with CTL Epitope Peptides from HIV-1 or Ovalbumin and the Mucosal Adjuvant Cholera Toxin Induces Peptide-Specific CTLs and Protection Against Tumor Development in Vivo," <i>J. Immunol.</i> 158:834-841 (1997).				<input type="checkbox"/>
	BJ	Shirai <i>et al.</i> , "Broad Recognition of Cytotoxic T Cell Epitopes from the HIV-1 Envelope Protein with Multiple Class I Histocompatibility Molecules," <i>J. Immunol.</i> 148:1657-1667 (1992).				<input type="checkbox"/>
	BK	Shirai <i>et al.</i> , "Helper-Cytotoxic T Lymphocyte (CTL) Determinant Linkage Required for Priming of Anti-HIV CD8+ CTL in Vivo with Peptide Vaccine Constructs," <i>J. Immunol.</i> 152:549-556 (1994).				<input type="checkbox"/>

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				Examiner Name	Nicole Kinsey
Sheet	5	of	5	Attorney Docket Number	015280-368240US

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	BL	Takahashi <i>et al.</i> , "An Immunodominant Epitope of the Human Immunodeficiency Virus Envelope Glycoprotein Gp160 Recognized by Class I Major Histocompatibility Complex Molecule-Restricted Murine Cytotoxic T Lymphocytes," <i>Proc. Natl. Acad. Sci. USA</i> 85:3105-3109 (1988).			<input type="checkbox"/>
	BM	Takahashi <i>et al.</i> , "Induction of Broadly Cross-Reactive Cytotoxic T Cells Recognizing an HIV-1 Envelope Determinant," <i>Science</i> 255:333-336 (1992).			<input type="checkbox"/>
	BN	Takeshita <i>et al.</i> , "Molecular Analysis of the Same HIV Peptide Functionally Binding to Both a Class I and a Class II MHC Molecule," <i>J. Immunol.</i> 154:1973-1986 (1995).			<input type="checkbox"/>
	BO	Yamamoto <i>et al.</i> , "Mutants in the ADP-ribosyltransferase Cleft of Cholera Toxin Lack Diarrheogenicity but retain adjuvanticity," <i>J. Exp. Med.</i> 185:1203-1210 (1997).			<input type="checkbox"/>
	BP	Yamamoto <i>et al.</i> , "A nontoxic mutant of cholera toxin elicits Th2-type responses for enhanced mucosal immunity," <i>Proc. Natl. Acad. Sci. USA</i> 94:5267-5272 (1997).			<input type="checkbox"/>
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